

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1111

To amend title 35, United States Code, with respect to patents on  
biotechnological processes.

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IN THE SENATE OF THE UNITED STATES

AUGUST 2 (legislative day, JULY 10), 1995

Mr. HATCH (for himself and Mr. KENNEDY) introduced the following bill;  
which was read twice and referred to the Committee on the Judiciary

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## A BILL

To amend title 35, United States Code, with respect to  
patents on biotechnological processes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. BIOTECHNOLOGICAL PROCESS PATENTS; CON-**  
4                       **DITIONS FOR PATENTABILITY; NONOBVIOUS**  
5                       **SUBJECT MATTER.**

6       Section 103 of title 35, United States Code, is  
7       amended—

8               (1) by designating the first paragraph as sub-  
9       section (a);

1           (2) by designating the second paragraph as  
2       subsection (c); and

3           (3) by inserting after the first paragraph the  
4       following:

5       “(b)(1) Notwithstanding subsection (a), and upon  
6       timely election by the applicant for patent to proceed  
7       under this subsection, a biotechnological process using or  
8       resulting in a composition of matter that is novel under  
9       section 102 and nonobvious under subsection (a) of this  
10      section shall be considered nonobvious if—

11           “(A) claims to the process and the composition  
12      of matter are contained in either the same applica-  
13      tion for patent or in separate applications having the  
14      same effective filing date; and

15           “(B) the composition of matter, and the process  
16      at the time it was invented, were owned by the same  
17      person or subject to an obligation of assignment to  
18      the same person.

19       “(2) A patent issued on a process under paragraph  
20      (1)—

21           “(A) shall also contain the claims to the com-  
22      position of matter used in or made by that process,  
23      or

24           “(B) shall, if such composition of matter is  
25      claimed in another patent, be set to expire on the

1 same date as such other patent, notwithstanding  
2 section 154.

3 “(3) For purposes of paragraph (1), the term  
4 ‘biotechnological process’ means—

5 “(A) a process of genetically altering or other-  
6 wise inducing a single- or multi-celled organism to—

7 “(i) express an exogenous nucleotide se-  
8 quence,

9 “(ii) inhibit, eliminate, augment, or alter  
10 expression of an endogenous nucleotide se-  
11 quence, or

12 “(iii) express a specific physiological char-  
13 acteristic not naturally associated with said or-  
14 ganism;

15 “(B) cell fusion procedures yielding a cell line  
16 that expresses a specific protein, such as a  
17 monoclonal antibody; and

18 “(C) a method of using a product produced by  
19 a process defined by (A) or (B), or a combination  
20 of (A) and (B).”.

21 **SEC. 2. PRESUMPTION OF VALIDITY; DEFENSES.**

22 Section 282 of title 35, United States Code, is  
23 amended by inserting after the second sentence of the first  
24 paragraph the following: “Notwithstanding the preceding  
25 sentence, if a claim to a composition of matter is held in-

1 valid and that claim was the basis of a determination of  
2 nonobviousness under section 103(b)(1), the process shall  
3 no longer be considered nonobvious solely on the basis of  
4 section 103(b)(1).”.

5 **SEC. 3. EFFECTIVE DATE.**

6       The amendments made by section 1 shall apply to  
7 any application for patent filed on or after the date of  
8 enactment of this Act and to any application for patent  
9 pending on such date of enactment, including (in either  
10 case) an application for the reissuance of a patent.

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